Fast Track Drug Development Programs: Designation and Review Programs
SOPP 8414
Appendix 2
Fast Track Designation Denied Letter

Our Reference: BB-IND [XXXX/XXX]

[SPONSOR'S NAME]
[INSTITUTION'S NAME]
[ADDRESS]

Dear [SPONSOR'S NAME:]

Reference is made to your **Investigational New Drug Application (IND)** for [PRODUCT NAME]. We also refer to your submission of [DATE], received on [DATE] requesting designation as a Fast Track Product pursuant to Section 506 of the Food, Drug, and Cosmetic Act.

We have reviewed your request for Fast Track designation for [CONDITION]. Designation as a Fast Track Drug Development Program cannot be granted at this time because [REASON FOR DENIAL]. Should you desire further consideration, please submit a new request along with your revised development plan.

For further information regarding Fast Track Drug Development Programs, please refer to the FDA document "Guidance for Industry on Fast Track Drug Development Programs: Designation, Development, and Application Review". This document is available on the internet at http://www.fda.gov/cber/guidelines.htm or may be requested from the Office of Communications, Training, and Manufacturers Assistance, at (301) 827-1800.

If you any have questions, please contact [RPM NAME], Division of [DIVISION NAME], at (301) 827-[XXXX].

Sincerely yours,

[DIRECTOR'S NAME]
Director
Division of [XXXXX]
Office of [XXXX]
Research and Review
Center for Biologics
Evaluation and Research

Application Number [BLA/IND/NDA/510(k)/PMA] _____

Letter Type: FAST TRACK DESIGNATION DENIED (FD)

Cc: Clinical Trial Branch Chief
Clinical Trial Branch/Division Special Assistant
HFM-110/RIMS
HFM-4/QAS
Office Director
HFM-500/B. Goldman
Review Committee
Division Regulatory Project Manager
All Office Division Directors

History

File Name

Concurrence box

Office	Name/Signature	Date